REMARKS

This is in response to the Office Action mailed on July 19, 2007, in which claims 1-38 were pending, and claims 8-10, 14, 16, 35 and 38 were withdrawn from consideration. Claims 1-7, 11-13, 15, 17-34, 36 and 37 were rejected over the prior art, and claims 1, 2, 4-9, 21-23 and 29 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 2-5, 7-11, 14, 22, 24, 28 and 29 of copending application 10/300,078. As further explained below, Applicant traverses both rejections. Claims 17-19, 21, 22 and 37 are amended to clarify the invention. The application containing pending claims 1-38 is in condition for allowance. Reconsideration and notice to that effect is respectfully requested.

Applicant respectfully thanks the Examiner for the telephone interview conducted between the undersigned and the Examiner on September 25, 2007. Eduardo Robert (the examiner's supervisor), and Matt Kyle (General Counsel of Assignee Millennium Medical Technologies, Inc.), were also telephonically present. The combining of different portions of the Huebner reference as set forth in the July 19, 2007 Office Action was discussed. It was agreed that a) Applicant's arguments appeared to overcome at least some of the prior art rejections, and b) Applicant would place such arguments in writing for further consideration by the Examiner.

The Office Action rejected claims 1-7, 11-13, 15, 17-33 and 36 as anticipated by Huebner. Applicant respectfully traverses this rejection. In making the rejection, the Office Action combined elements from three separate embodiments of Huebner, namely, the embodiment of FIG. 14, the embodiment of FIG. 21 and the embodiment of FIG. 22. These three figures from Huebner represent separate and distinct devices. As explained during the telephone interview, if the reference discloses one embodiment with elements A, B1 and C1, and a second embodiment with elements A, B2 and C2, while it might be proper to make a rejection based upon combining elements A, B1 and C2, it would not be proper to make a rejection based upon combining elements A, B1, B2 and C1, particularly if elements B1 and B2 are disclosed to be mutually exclusive alternatives.

More specifically, turning to the specific content of the rejection, the Office Action started with the embodiment of Huebner FIG. 22, shown below:

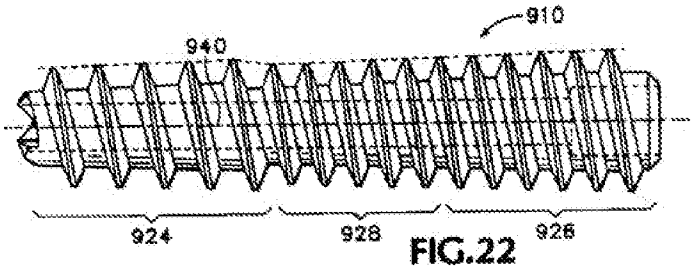

FIG.22

Sections 928 and 926 were identified as the "bone exterior section".

The Office Action then reached to the embodiment of Huebner FIG. 21, shown below, as teaching "a compression engagement on a distal end of the bone exterior section".

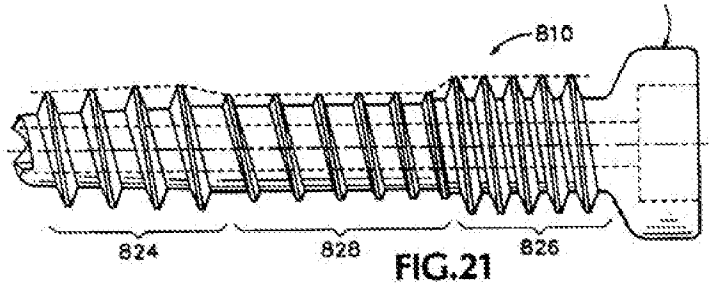

FIG.21

As understood, this combination proposed in the Office Action would look like this:

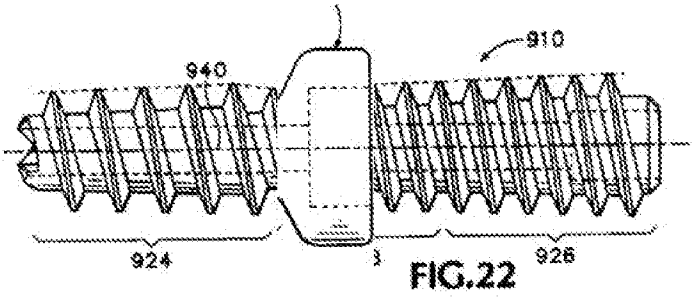

FIG.22

To the contrary, while it might be either disclosed or suggested in Huebner to place head 846 on a proximal end of the FIG. 22 device, Huebner does not disclose or suggest to make the depicted combination with head 846 on the distal end of sections 928 and 926. It would not be obvious to place head 846 from Huebner FIG. 21 on a **distal** end of the intermediate section 928 from Huebner FIG. 22, as such placement would render the threads on the intermediate section 928 and the threads on the trailing section 926 useless. There is no teaching or suggestion in Huebner or elsewhere in the art to place head 846 from Huebner FIG. 21 on a **distal** end of the intermediate section 928 from Huebner FIG. 22. The inventive method as defined by independent claim 1 requires the bone

exterior section to make up at least one third of a total length of the device, with a compression engagement on a distal end of the bone exterior section. Huebner shows no headed device wherein the head makes up at least one third of a total length of the device. The rejection of claim 1, based upon combining head 846 from Huebner FIG. 21 in the middle of the structure of Huebner FIG. 22, should be withdrawn.

The same type of rationale can be applied to show that all of claims 1-38 are patentable over Huebner under both an anticipation and an obviousness analysis. Claims 4 and 6, for instance, require the compression engagement to be provided by a nut rotatably supported on the threads of the bone exterior section. The head 846 of Huebner FIG. 21 clearly does not disclose or suggest a nut rotatably supported on threads of the bone exterior section. The Office Action stated that "the compression engagement is provided by a nut (FIG. 14 below) rotatably supported on the threads of the bone exterior section. FIG. 14 of Huebner shows a placement sleeve 140, which is a tool for placing the screw 110, not part of the implanted device. The placement sleeve 140 does not disclose or suggest a nut rotatably supported on threads of the bone exterior section which is provided as part of the implanted device. All embodiments of Huebner use threads inside the bone fragment to hold the bone fragment in place. Nor does Applicant understand how the placement sleeve 140 of Huebner FIG. 14 could be used simultaneously with the head 846 of Huebner FIG. 21. The headed screw of Huebner FIG. 21 and the placement sleeve 140 of Huebner FIG. 14 appear to be mutually exclusive alternatives: neither is disclosed or suggested for use with the other.

Nor do either head 846 of Huebner FIG. 21 or placement sleeve 140 disclose or suggest the profile required by claims 8 and 9. The portions of head 846 identified in the Office Action for "gentle slope" and "steep slope", in particular, are on the distal side of the head 846 for insertion, not on the proximal side of the compression engagement for removal as required by claim 8 and 9.

Several statements in the Office Action (Office Action, page 6) about the anchor threads being self tapping proximally, about the non-engaging fragment section being substantially smooth and cylindrical, about the major and minor diameters of the fragment exterior section, and about a pointed proximal drill tip for reverse insertion are not supported by the Huebner FIG. 22 drawings.

Further, it should be noted that heading "non-engaging fragment section" identified in the Office Action on the drawing of Huebner FIG. 22 is not a section of the screw at all, but rather the minor diameter of the anchor threads. The minor diameter of the anchor threads cannot be considered a non-engaging fragment section, because the anchor threads (both major and minor diameters) engage the bone. Note that there is no leading structure which would prevent the minor diameter of the Huebner FIG. 22 anchor threads from contacting and engaging the bone. Claims 1 and18 require that the various sections of the device extend longitudinally about the shaft axis, further clearly distinguishing what is meant by the "non-engaging fragment section" which is significantly different from the minor diameter of the anchor threads. The Office Action stated that the "non-engaging fragment section is the small portion of the shaft indicated by the line that is located between adjacent threads", but at best this portion is a helical wrap (i.e., the minor diameter), and cannot be said to be cylindrical as required in claims 11 and 14.

Of the three devices of Huebner specified in the Office Action, only the device of FIG. 14 has a non-engaging fragment section (i.e., which fits entirely within the shadow of the anchor threads and does not engage the threads left in the bone fragment, so the bone fragment can slide longitudinally relative to the non-engaging fragment section); however, the device of FIG. 14 is implanted entirely within the bone without a compression engagement.

The method claims of the present invention are distinctly patentable over any method disclosed or suggested by Huebner. In analyzing Applicant's method claims for patentability, the issue is not whether the prior art device has the claimed structural limitation and could possibly be used in accordance with Applicant's claimed method, but rather whether the prior art reference discloses or suggests that its device actually be used in accordance with Applicant's claimed method. Claim 28, for example, requires screwing of a structure, with a bone penetration section shorter than the bone exterior section, first through the fragment and then further screwing into the anchor bone. To meet the limitations of the claim, the implant must have a bone exterior section which is longer than the bone penetration section in use after the two screwing acts. Huebner does not disclose or suggest any device which, after the two screwing acts, still has a bone exterior section which is longer than the bone penetration section.

Claim 29 requires, with the bone anchor section advanced into the bone fragment but prior to the act of further screwing the device into the anchor bone, manipulating the bone exterior section to reposition or bias the bone fragment relative to the anchor bone. The fact that a Huebner device might be able to be used in this "joystick" method of manipulating the bone fragment, is immaterial; what matters is whether Huebner disclosed or suggested such a method. In the series of Huebner FIGS. 11-14, the bone fragment is only manipulated after the device is screwed into the anchor bone. Huebner does not disclose or suggest using the device for manipulation of the bone fragment prior to screwing into the anchor bone.

With regard to the "healing duration" required in claims 1, 8, 17, 18, 21 and 35, the Office Action found such limitations met in FIGS. 11-14 of Huebner, stating, "since some healing, though minimal, will occur while the compression engagement is being utilized, and the compression engagement will be removed from the body upon emplacement of the compression device." Office Action, page. 8. To the contrary, the placement sleeve 140 of Huebner is only used during surgical placement of the screw. As would be understood by any surgeon, the surgical placement of an implant is not a "healing duration", but rather is a traumatic event from which the body needs time to rest and heal afterward. Huebner does not disclose or suggest that placement sleeve 140 should be left in the patient's body for a healing duration. See the specification at page 6, lines 16-18: "The CTCD 10 of the present invention is intended to be surgically implanted and left within the patient for a healing duration while the fragment 30 attaches and grows together to the anchor bone 32." Any interpretation of "healing duration" as being fulfilled during a surgical procedure is unreasonably broad.

Similarly, Huebner, alone or in combination with Taras, does not disclose or suggest the removing act required in claim 34 of the cutting act required in claim 37. The Office Action noted that, "Taras et al. disclose a method of using a fracture fixation device (Fig. 1, ref. 10) including a step of cutting off a portion of the shaft (paragraph 0033) in order to create a flush connection (paragraph 0033). However, claims 34 and 37 are using removing/cutting for the opposite of a flush connection, i.e., cutting proximally behind the compression engagement. There is no disclosure or suggestion of how the cutting step of Taras could be used to cut off a portion of Huebner proximal to

the compression engagement. With full view and consideration of Taras, a worker skilled in the art would find no motivation or teaching to cut off any portion of the placement sleeve 140 of Huebner Fig. 14 or to cut off any portion of the head 846 of Huebner Fig. 21. The rejection of Applicant's method claims should be withdrawn.

The Office Action also provisionally rejected claims 1, 2, 4-9, 21-23 and 29 under the judicially created doctrine of obviousness-type double patenting over claims 2-5, 7-11, 14, 22, 24, 28 and 29 of copending application 10/300,078. This provisional rejection is traversed. Firstly, copending application 10/300,078 has not yet been allowed. More importantly, both the present application and application 10/300,078 were subject to restriction requirements between the apparatus claims and the method claims. In application 10/300,078, Applicant elected the apparatus claims. (See March 21, 2005 Office Action and April 19, 2005 election). In the present application, Applicant elected the method claims. (See January 22, 2007 Office Action and April 3, 2007 election). Section 121 of the Patent Statute states, "A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application." Both the present application and copending application no 10/300,078 enjoy the benefit of section 121 and cannot be used as a basis for rejecting the other. The provisional double patent rejection should be withdrawn.

The application containing pending claims 1-38 is in condition for allowance. Reconsideration and notice to that effect is respectfully requested. The Examiner is invited to contact the undersigned at the telephone number listed below if such a call would in any way facilitate allowance of the application.

Respectfully submitted,

SHEWCHUK IP SERVICES, LLC

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By /JDS/

Jeffrey D. Shewchuk, Reg. No. 37,235
3356 Sherman Court, Ste. 102
Eagan, MN 55121
Telephone: (651) 331-9558
Fax: (651) 688-3348

JDS: